

IN THE CLAIMS

Please amend the claims as follows:

Claims 1-20 (Cancelled).

Claim 21 (Previously Presented): A composition, comprising:

an extremely poorly water-soluble drug; and

a porous silica material;

wherein:

the composition is obtained by treating a mixture comprising the porous silica material and the extremely poorly water-soluble drug with a supercritical fluid or subcritical fluid of carbon dioxide;

the extremely poorly water-soluble drug has a solubility in water at 25 °C of less than 10 µg/mL prior to treatment;

the porous silica material has an average pore diameter of from 1 to 20 nm, a total pore volume of pores having diameters within $\pm 40\%$ of the average pore diameter accounts for at least 60% of a volume of all pores of the porous silica material, and the porous silica material has an X-ray diffraction pattern including at least one peak at a position of a diffraction angle (2θ) corresponding to a d value of at least 1 nm; and

the composition is suitable for oral administration.

Claim 22 (Previously Presented): The composition according to claim 21, wherein the porous silica material has a specific surface area of from 100 to 2,000 m²/g.

Claim 23 (Previously Presented): The composition according to claim 21, wherein a mixing ratio the porous silica material to the extremely poorly water-soluble drug is from 0.1:1 to 1,000:1.

Claim 24 (Previously Presented): The composition according to claim 21, wherein the extremely poorly water-soluble drug comprises 2-benzyl-5-(4-chlorophenyl)-6-[4-(methylthio)phenyl]-2H-pyridazin-3-one.

Claim 25 (Withdrawn – Currently Amended): A medicinal preparation comprising:
the composition according to claim 21; and
an additive.

Claim 26 (Withdrawn): A process for producing the composition according to claim 21, comprising:

placing a porous silica material and an extremely poorly water-soluble drug in a pressure-resistant vessel;
filling the pressure-resistant vessel with carbon dioxide;
maintaining the vessel at a temperature and pressure such that the carbon dioxide is maintained as a supercritical fluid or a subcritical fluid; and
discharging the carbon dioxide to recover the resulting composition;
wherein the porous silica material has an average pore diameter of from 1 to 20 nm, a total pore volume of pores having diameters within $\pm 40\%$ of the average pore diameter accounts for at least 60% of a volume of all pores of the porous silica material, and the porous silica material has an X-ray diffraction pattern including at least one peak at a position of a diffraction angle (2θ) corresponding to a d value of at least 1 nm.

Claim 27 (Withdrawn): The process of claim 26, wherein a weight ratio of the extremely poorly water-soluble drug to the supercritical fluid or subcritical fluid of carbon dioxide is from 1:1 to 1:1,000,000.

Claim 28 (Withdrawn): The process of claim 26, wherein maintaining the vessel comprises maintaining the vessel at a temperature of from – 40 to 100°C.

Claim 29 (Withdrawn): The process of claim 26, wherein maintaining the vessel comprises maintaining the vessel at a pressure of from 1 to 50 MPa.

Claim 30 (Withdrawn): The process of claim 26, wherein the porous silica material and the extremely poorly water-soluble drug are maintained in contact with the supercritical fluid or subcritical fluid of carbon dioxide for a period of from 1 minute to 24 hours.

Claim 31 (Withdrawn): A process for producing a composition according to claim 21, comprising:

placing a porous silica material and an extremely poorly water-soluble drug in a pressure-resistant vessel;

maintaining the vessel at a temperature at which carbon dioxide is in the form of a supercritical fluid or a subcritical fluid;

filling the vessel with carbon dioxide at a pressure such that carbon dioxide is in the form of a supercritical fluid or a subcritical fluid;

treating the porous silica material and the extremely poorly water-soluble drug with the supercritical fluid or subcritical fluid of carbon dioxide; and

discharging carbon dioxide to recover the resulting composition;
wherein the porous silica material has an average pore diameter of from 1 to 20 nm, a total pore volume of pores having diameters within $\pm 40\%$ of the average pore diameter accounts for at least 60% of a volume of all pores of the porous silica material, and the porous silica material has an X-ray diffraction pattern including at least one peak at a position of a diffraction angle (2θ) corresponding to a d value of at least 1 nm.

Claim 32 (Withdrawn): The process according to claim 31, wherein a weight ratio of the extremely poorly water-soluble drug to the supercritical fluid or subcritical fluid of carbon dioxide is from 1:1 to 1:1,000,000.

Claim 33 (Withdrawn): The process according to claim 31, wherein treating the porous silica material and the extremely poorly water-soluble drug comprises treating at a temperature of from – 40 to 100°C.

Claim 34 (Withdrawn): The process according to claim 31, wherein treating the porous silica material and the extremely poorly water-soluble drug comprises treating at a pressure of from 1 to 50 MPa.

Claim 35 (Withdrawn): The process according to claim 31, wherein treating the porous silica material and the extremely poorly water-soluble drug comprises treating for a period of from 1 minute to 24 hours.